ISSUES FOR IACUCS

Use of Electronic Communications for IACUC Functions

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INTRODUCTION

The Public Health Service (PHS) Policy on Humane Care and Use of Laboratory Animals (Policy) describes 8 basic institutional animal care and use committee (IACUC) functions (PHS 1986, IV.B.1-8). These functions vary in complexity and include reviewing the overall animal program and inspecting the animal facilities every 6 months; reviewing and approving animal study proposals initially and at least once every 3 years thereafter (annually under U.S. Department of Agriculture Animal Welfare regulations [9 CFR 1-3]); reviewing concerns about the animal care and use program; making recommendations to the institutional official about any aspect of the institution’s programs, facilities, or training; and suspending activities involving animals under certain circumstances.

Traditionally, these activities have been accomplished through meetings physically attended by members of the IACUC. The traditional meeting provides the kind of environment that is most conducive to thoughtful deliberation and interaction and is still regarded as the optimum forum for many of the IACUC functions.

With the advent of technological advances in communication capabilities, however, questions have arisen about the acceptability of using telephone conference calls, audiovisual conferencing, facsimile transmission (fax), and electronic mail (e-mail) as well as postal mail, in lieu of face-to-face meetings for the conduct of IACUC business.

Because of the diversity of activities that IACUCs are called upon to engage in, it is not possible to anticipate every situation in which each alternative to a traditional meeting may be applicable. Nevertheless, the Office for Protection from Research Risks (OPRR) of the PHS considers that there may be circumstances in which one or more of the foregoing options may be used. A discussion of several such circumstances, grouped by categories, is as follows:

GENERAL ISSUES

Animal Welfare Assurance

The Animal Welfare Assurance (Assurance) on file with OPRR must contain a description of the procedures that the IACUC will follow to fulfill the requirements of the PHS Policy. OPRR expects that all approved Assurances are complete and accurate and that they reflect the use of any nontraditional procedures for conducting IACUC business.

Distribution of Information

The conveyance, by fax or e-mail, of information such as the institutional Assurance; animal study proposals; agendas and minutes of meetings; institutional policies and standard operating procedures; reports, announcements, or correspondence from oversight or regulatory agencies; and other matters related to the institutional animal care and use program for consideration and review by IACUC members would be regarded as appropriate.


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Definition of “Convened Quorum”

A “convened quorum” generally means a meeting of more than 50 percent of the members of a group, that is, the minimum number necessary to conduct official business. As a standard operating procedure, this should be the traditional gathering of people in a meeting room at the same time. Other forms that provide the same opportunities for members to deliberate interactively with a quorum of other members of the committee may be functionally equivalent. Conference calls, audio-video conferences, and possibly some forms of highly interactive on-line computer discussion groups may qualify in exceptional circumstances.

As an operating standard, the conduct of IACUC meetings should allow greater opportunity for members to interact than is permitted by simple fax or e-mail messages. However, in exceptional circumstances, telephone and audiovisual conferencing may be appropriate alternatives to face-to-face meetings. To be considered a valid IACUC meeting, all members must be given ample prior notice to participate, and at least a quorum of the voting members must be convened on the same conferencing (telephone or audiovisual) line. In addition, the quorum of IACUC members must be in direct communication with each other and be given full opportunity to participate for the duration of the meeting. In either case, minutes of the meetings must be compiled and maintained on file as required by oversight and regulatory agencies.

IACUC meetings at which voting occurs warrant special consideration. While telephone conferencing and audiovisual conferencing may be appropriate alternatives to face-to-face meetings in exceptional circumstances, members must be given ample prior notice to participate and be provided in advance with the materials or information on which they will vote. The meeting must consist of at least a quorum of the voting members convened on the selected telephone or audio-visual network who are in direct communication with each other and given a genuine opportunity for deliberation and interaction for the duration of the meeting. It is especially important to note that using individual one-on-one meetings, the telephone, fax, or e-mail to poll or otherwise obtain members’ votes outside of a convened quorum does not meet PHS Policy requirements. As with other IACUC functions, documentation must be compiled and kept on file in accordance with oversight and regulatory agencies.

Polling

Polling is defined as sequential, one-on-one communication, either in person or via telephone, e-mail, fax, U.S. mail, or by other similar means. Polling is an appropriate mechanism for providing all committee members with the opportunity to call for full review of a protocol prior to initiating the “designated reviewer” method of protocol review described below. It may also be appropriate as a mechanism for distributing and reviewing drafts of meeting minutes or reports.

The simple polling of IACUC members does not, however, satisfy the definition of a meeting of a convened quorum and should not be used for conducting IACUC business that requires the vote of a convened quorum of the committee. For example, polling should not be considered a valid method of voting under the “full committee” review method of protocol review and is not an acceptable substitute for having a vote of a convened quorum on the suspension of a previously approved activity involving animals.

Security

Institutions using innovative modes of communication must be aware of the potential security problems inherent in the method chosen. Some material considered by IACUCs should be treated as privileged or confidential, especially prior to final committee action. In the case of trade secrets, such information may be protected by law (7 USC 2157, section 27). Because of widespread reports of unauthorized access to computer records, the use of available computer security measures such as passwords, controlled access, and encryption should be considered.

Signatures

Many IACUC activities involve the need for documenting votes or verifying committee approval. Letters and reports often require signatures in order to be legally binding. Techniques for providing such legally acceptable “electronic signatures” are being developed by the computer industry to address this problem. Currently, electronic communication is frequently used to facilitate the rapid conduct of business with signed original documents to follow for the permanent record.

PROTOCOL REVIEW

Both the PHS Policy and the USDA regulations recognize 2 methods of protocol review. Although institutions frequently introduce procedural variations and assign different names to their processes, all protocol reviews must be consistent with one of the following prescribed methods:

Full Committee Review

Full committee review requires a meeting of a convened quorum of the IACUC. As outlined in the definition of convened quorum, full committee review is an example of an
IACUC function that requires committee deliberation, interactivity, and voting, and which could be accomplished, in exceptional circumstances, through a carefully devised mechanism using telephone conferencing, audiovisual conferencing, or some other form of highly interactive electronic communication.

Designated Member Review

The other recognized procedure for protocol review is called designated member review. In this method, prior to review, all members are provided with the necessary information concerning the proposed research projects. All members are then given the opportunity to request full committee review. If no member calls for full committee review, then the IACUC Chair may designate one or more qualified IACUC members to review proposed research projects and to have authority to approve, require modifications in (to secure approval), or request full committee review of those research projects.

Polling is an acceptable mechanism for providing all IACUC members with the prior opportunity to call for full review. It should be noted that the polling of IACUC members in this instance is not an approval vote on the proposed research. Records of such polling, however, are useful to document that the opportunity for members to call for full committee review has been provided.

SUSPENSION OF AN ACTIVITY

The PHS Policy and USDA regulations prescribe procedures that must be followed in order to suspend a previously approved activity. Such action requires a review of the matter at a convened quorum of the IACUC and a suspension vote by a majority of the quorum present. Innovative mechanisms that meet the description of convened quorum could be used to perform this IACUC function.

REPORTING

All official IACUC reports are considered to be the result of “full committee” action. Thus, endorsement of final reports issued under the IACUC aegis should include the opportunity for full participation and the opportunity for minority views to be expressed and recorded. This function should normally occur at a meeting of a convened quorum of the IACUC. Alternate methods of achieving a convened quorum may also be applicable to this IACUC function.

SEMIANNUAL REVIEW AND INSPECTION

Semiannual program review and facility inspection may be conducted in a variety of ways, as described in the PHS Policy and USDA regulations. However, final reports must be reviewed and endorsed by a convened quorum as described above.

SUMMARY

The PHS Policy concept of institutional self-regulation with local IACUC oversight evolved from similar mechanisms applied to the protection of human subjects in research. As with the Institutional Review Board (IRB) for human subjects, assumptions regarding the general environment in which oversight of animal related research takes place were included in the design of prescribed oversight mechanisms. One of those assumptions was that committees normally function through periodic meetings where members would consider, deliberate, and vote on matters within their purview. This model did not anticipate the technological advances that would make it possible to approximate the traditional meeting environment from greater distances and with greater ease and speed than was the norm at that time.

Although the traditional meeting is still seen as the optimum environment for fulfilling the intent of the PHS Policy, OPRR recognizes the new communications tools available and the need for flexibility in the ways that institutions may comply with the PHS Policy in the many diverse settings encountered. For these reasons, several criteria have been provided for establishing alternate methods that may be considered functionally equivalent to meetings of a convened quorum under exceptional circumstances. Two of those criteria are that the alternate approach must include a high degree of interactivity and allow for careful deliberation of sensitive issues. Another is that a quorum of IACUC members must be in direct communication with each other and be given full opportunity to participate for the duration of the meeting. Institutions are reminded that details of their IACUC procedures, especially those that may vary from those outlined in the PHS Policy, should be thoroughly described in the institutional Assurance and submitted for OPRR review.

REFERENCES

Animal Welfare Regulations. Code of Federal Regulations, Title 9 (Animals and Animal Subproducts), Subchapter A (Animal Welfare), Parts 1-3 (9 CFR 1-3). (Available from Regulatory Enforcement and Animal Care, U.S. Department of Agriculture, 4700 River Road, Room 2D01, Riverdale MD 20737)